

Serial No. 10/660,775

**REMARKS**

Claims 1-10, 14-28 remain pending in this application, wherein claims 23-28 have been withdrawn from consideration. Claims 3 and 8 have been amended and claims 11, 12, 13, and 29 have been cancelled without prejudice or disclaimer, to place the application in better condition for allowance or appeal.

Entry of the above amendment is respectfully requested. The amendment serves to place the application into condition for allowance and/or to overcome formal matters raised by the Examiner. The amendment does not raise any new issues or require any further consideration, nor does the amendment introduce new matter. Therefore, entry of the amendment is believed appropriate and is respectfully requested.

**Interview Summary**

Applicants appreciate the courtesies extended by the Examiner during the interview of June 1, 2006. As indicated in the Examiner's Interview Summary, the propriety of the §112 rejection was discussed and general agreement was reached that bodily incorporating the figures recited in each of dependent claims 3 and 8, respectively, would overcome the rejection (no such limitation was needed in independent claim 1). Regarding the prior art rejections, it was pointed out that the x-ray diffraction data was already of record showing that form I and form II are in fact different crystalline forms. Because no x-ray data existed for the amorphous form, it was suggested that applicants

Serial No. 10/660,775

submitting such data in declaration form. However, for convenience, claim 12 has been cancelled to expeditiously resolve the issue.

**Rejections under 112**

Claims 1, 3, 8, 11, and 12 have been rejected under 35 USC § 112, second paragraph, as allegedly being indefinite because they refer to a drawing figure (claims 3 and 8) or don't recite the complete x-ray diffractogram (claims 1, 11, and 12). These rejections are respectfully traversed.

As the Examiner understands, the present invention is directed to a polymorph; i.e., a different stacking arrangement of the bicalutamide molecules. This different stacking or lattice arrangement provides for some different physical properties in comparison to the known crystalline form. These different properties include different IR spectra and different x-ray diffractogram. But these physical properties merely reflect the underlying structural difference between the present invention and the prior art, namely a difference in stacking of the bicalutamide. This new stacking arrangement was denominated by the inventors as "form II." Thus claim 1 covers this new crystalline form of bicalutamide, regardless of what physical test is used to prove its existence.

During the interview, the Examiner agreed that form II had meaning, especially in light of the specification and that it was unnecessary to recite the x-ray diffractogram in claim 1. However, the Examiner maintained that reciting the actual drawing figure called

Serial No. 10/660,775

for in dependent claims 3 and 8 was preferred. Accordingly, applicants have amended claims 3 and 8 as agreed during the interview. In view of the amendments and previous remarks, the claims are clearly definite within the meaning of § 112, second paragraph. Reconsideration and withdrawal of this rejection are requested.

**Rejections over Ekwuribe and Tucker**

Claims 1-11 and 14-22 have been rejected under 35 USC § 102(a)/(e) and § 103 over Ekwuribe, US 6,583,306 (US '306) as alleged being anticipated or rendered obvious. Further claims 13-22 have been rejected under 35 USC § 102(b) and § 103 as allegedly being anticipated by, or rendered obvious by, Tucker, US 4,636,505 (US '505). These rejections are respectfully traversed.

Neither US '306 nor US '505 teach or suggest forming bicalutamide as crystalline form II. That the claimed form II polymorph is a different, novel crystal structure over the known form is shown by comparing figure 1 (form I) with figure 2 (form II produced in example 1 of the specification). The known crystalline form (form I) has a different pattern which is indicative of a different stacking arrangement than the claimed form II. Similarly, the difference between the claimed form II and the conventional form I can be seen in comparing the IR spectrums in figure 3 (form I) with figures 4 or 5 (form II). Thus, the data shows that form I and form II are different. Accordingly the instant claims are novel over the cited prior art.

Serial No. 10/660,775

Moreover, nothing in US '306 or US '505 teaches or suggests forming another crystalline form of bicalutamide. As the Examiner is aware, not all substances can exist in multiple crystalline forms (i.e., not all compounds are polymorphic). And nothing in the cited prior art suggests seeding with form II crystals and/or using higher precipitation temperatures, etc., in order to form form II crystalline material (see pages 8-9 of the present specification). Accordingly, there is no suggestion or reasonable expectation of success in the cited prior art to form the claimed subject matter. The mere fact that it might have been possible to make another crystalline material is not adequate motivation to render the specifically claimed crystalline material obvious. In the absence of a *prima facie* case of obviousness, the rejection is improper and must be withdrawn.

For the above-mentioned reasons, and in view of the traversals set forth in the Request for Reconsideration filed November 21, 2005, which are incorporated herein by reference, each of the prior art rejections is in error and withdrawal thereof are respectfully requested.

#### **Provisional Double Patenting**

Claims 13-22 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 or 11 of Ortega et al, Serial No. 10/842,632. This rejection is respectfully traversed.

Serial No. 10/660,775

Although applicants maintain that the double patenting rejection is improper, as a matter of expediency, applicants point out that this provisional double patenting rejection should be withdrawn as premature. Specifically, the co-pending application has yet to receive a first office action on the merits, while the present application is believed to be in condition for allowance. Therefore, the Examiner should withdraw this rejection and allow the present application to issue. See MPEP 804, Section I.B. (last paragraph). To the extent necessary (and applicants believe that it is not necessary), the USPTO can take up any double patenting issue in the co-pending application in due course. Accordingly, withdrawal of this provisional rejection is requested.

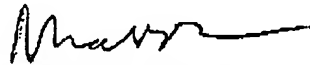
### Conclusion

In view of the above remarks, all claims pending in the present application define novel, patentable subject matter. Reconsideration of each of the rejections and allowance of the present application are requested. Further, since claim 1 is allowable, then withdrawn process claims 23-28 should be rejoined and likewise allowed (see MPEP § 821.04).

Serial No. 10/660,775

Should the Examiner have any questions or concerns regarding the immediate allowability of this application, the Examiner is encouraged to contact applicants' representative, Mark R. Buscher (Reg. No. 35,006) at telephone number 703 753 5256.

Respectfully submitted,



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